SUMMARY OF THE REGULATORY COORDINATION COMMITTEE MEETING DECEMBER 16, 1999

The Regulatory Coordination Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Thursday, December 16, 1999, at 12:30 p.m. EST as part of the Fifth NELAC Interim Meeting in Washington, DC. The meeting was led by its chair, Dr. Michael Miller of the New Jersey Department of Environmental Protection. A list of action items is given in Attachment A. A list of participants is given in Attachment B. A summary of the committee's proposed language changes to the NELAC Standards prepared for the committee's distribution to interested parties is presented as Attachment C. *The purpose of the meeting was to discuss issues outlined in the committee's previously distributed agenda.*

INTRODUCTION

Dr. Miller opened the meeting, introduced the scribe, Ms. Lisa Greene, who then reviewed the meeting's ground rules and circulated an attendance sheet. The members of the committee introduced themselves. Dr. Miller noted that one state government member and one non-regulatory member were rotating off the committee and that the committee's one federal government member had resigned. He encouraged interested parties to volunteer for service on the committee. Dr. Miller also reviewed the afternoon's agenda. The minutes from the last committee meeting by teleconference were unanimously approved.

UNRESOLVED ISSUES

Scope of Fields of Testing

Dr. Carl Kircher has compiled a single comprehensive list of Fields of Testing under which each of the first eleven approved Accrediting Authorities (AAs) will offer NELAC accreditation. The list has been structured on a program-method-analyte basis and has been posted as an Excel® spreadsheet on the NELAC Website. There was some discussion of an essential subset consisting of minimum requirements for accreditation falling under the comprehensive list of Fields of Testing. A suggested a restructuring of the Fields of Testing. Dr. Miller tabled this issue to be addressed later in the committee's agenda under "New Business."

Infra-structure Necessary for States to Implement NELAC

Dr. Miller reviewed progress to date in developing the infra-structure necessary for states to implement NELAC. He noted that each individual state is working to integrate its database and that the NELAC Database Committee has set a deadline of July 1, 2000, to have in place a workable national database. The NELAC Proficiency Testing Committee is moving forward with a list of parameter analytes. In the area of laboratory education and outreach, the NELAC Membership and Outreach Committee is making a concerted effort to collect information from as many sources as possible for inclusion on the NELAC Internet site. The Regulatory Coordination Committee also forwards materials that they receive to the Membership and Outreach Committee for their distribution to stakeholders.

Dr. Miller noted that progress in the development of state infrastructures is often a question of state resources. He noted that even states with established auditing programs would find that the NELAC accreditation process takes a great deal of time in terms of review of accreditation applications and data packages. He indicated that the Regulatory Coordination Committee would like feedback from AAs regarding the time investment necessary for a NELAC on-site assessment.

Dr. Miller then opened the issue to the floor for discussion. One participant noted that the Environmental Laboratory Advisory Board (ELAB) has been focusing on small laboratory issues. In their discussions ELAB has noted that small laboratories desire help with Standard Operating Procedures (SOPs) and Quality Manuals. He suggested that the first 11 Accrediting Authorities take on the task of developing template generic SOPs and Quality Manuals as a means of transitioning into NELAC, thereby aiding the development of state infra-structures.

FUTURE PLANS

Review of USEPA October 1999 Regulatory Agenda

The committee's comprehensive review of the United States Environmental Protection Agency (USEPA) October 1999 Regulatory Agenda has been tabled for the Sixth NELAC Annual Meeting. Dr. Kircher gave a brief overview, however, of significant regulatory changes. Most of the changes have occurred in the area of the Safe Drinking Water Act. Effective mid-September 1999, USEPA issued a new slate of unregulated contaminants for which public water systems must test. This slate of contaminants was presented in a bi-weekly meeting by teleconference to the 11 approved AAs and has been included in the Scope of Fields of Testing spreadsheet currently posted on the NELAC Website. On December 1, 1999, USEPA issued new approved test methods for drinking water analysis, consisting of three new methods for microbiological analysis, with a year 2000 effective date. These methods will be presented to the 11 approved AAs and may be included in the Scope of Fields of Testing spreadsheet. In the area of chemistry, USEPA issued a new approved method for herbicide testing (USEPA Method 515.3) and replaced USEPA Method 549.1 with USEPA Method 549.2. Since USEPA Method 549.2 does not constitute a major change to the test method, the Scope of Fields of Testing spreadsheet was merely renumbered. The Regulatory Coordination Committee has written a memo to the NELAC Quality Systems and On-site Assessment Committees notifying them of these regulatory changes.

Collection of State Regulations and Legislation for the Implementation of NELAC

In accordance with their charge, the Regulatory Coordination Committee will assemble recent state regulations and legislation for the implementation of NELAC and distribute this implementation information to other states.

USEPA Mandatory Agency-wide Quality System

Mr. George Avery reviewed USEPA Order 5360.1, dated July 16, 1998, which mandates an agency wide Quality System and applies to entities performing data collection for USEPA. Since this order applies to field activities and potentially the laboratory activities associated with them, the Regulatory Coordination Committee recommends that the documents associated with the order be reviewed by the appropriate NELAC committees to determine how they affect NELAC. A participant suggested that the committee also recommend through the NELAC Board of Directors (BoD) to USEPA that the Agency review the documents and evaluate their effect on NELAC.

Review of Sample Laboratory Application

Dr. Miller noted that Ms. Jeanne Mourrain, NELAC Director, has asked the Regulatory Coordination Committee to review the sample laboratory application currently posted on the NELAC Website to make sure that it is compliant with the July 1999 NELAC Standards and that it contains the information that the first 11 approved AAs have found necessary in their applications. The committee has requested example applications from each of the 11 AAs and intends to report to the Conference at the Sixth NELAC Annual Meeting in July 2000.

NEW BUSINESS

Restructuring of the NELAC Fields of Testing

Mr. George Avery led a review of proposed restructuring of the Fields of Testing, which is currently structured by program-method-analyte. He noted that although the test methods in the current Fields of Testing compendium are fairly consistent among the 11 approved AAs, the analytes listed under each of those methods are not consistent from state to state. Consequently, the Regulatory Coordination Committee proposes that the NELAC Scope of Accreditation be defined by matrix and test method. To this end, Mr. Avery has drafted proposed language changes for the NELAC Program Policy and Structure and Accreditation Process Standards as follows:

Proposed changes to the Program Policy and Structure Standard:

- Amend glossary definition of Field of Testing to read, "NELAC's approach to accrediting laboratories by matrix and method."
- Replace Section 1.8.1 with the following language:

  "The Accreditation Process will be based on the test method and matrix. The laboratory must meet the general requirements of Chapter 5, and the specific Quality Assurance requirements for the type of testing performed as outlined in Chapter 5, Appendix D. Accreditation will be granted for the matrix and method, for example, Water-Method 525.2.

  The laboratory must meet all relevant program requirements for the specific program for which testing is performed.

Accreditation for a method will include all analytes designated as within the scope of the method in the published method, as well as other analytes which may reasonably and legally be analyzed by the method, and for which the laboratory can successfully demonstrate capability."

- Delete Table 1.3.
- Add the following language to Section 1.6.5.1.4:

  "The committee develops a list of analytes relevant to each approved test method for inclusion in proficiency tests, and criteria for the evaluation of laboratory performance on proficiency tests."

Proposed changes to the Proficiency Testing Standard:

- Make the following language addition to Section 2.7.1:

  "A grade of 'acceptable' is awarded when the laboratory successfully analyzes 80% of the analytes defined for a field of testing."

Proposed changes to the Accreditation Process Standard:

- Replace "program-matrix-analyte" with "matrix-method" in Section 4.1.4.a, Section 4.1.4.b, Section 4.1.4.c, and Section 4.1.4.d.
- Replace "method" with "analyte," "analyte" with "matrix," and "matrix" with "method" in Section 4.1.4.c.

The committee opened the issue to the floor for discussion. It was noted that one major barrier to restructuring the Fields of Testing is the fact that USEPA regulations mandate test methods. It was also noted that USEPA regulations are worded "approval by analyte." A committee member asked how states that do not list individual analytes under their Fields of Testing are able to do so under USEPA regulations. No clear answer to this question was determined. It was also noted that the Scope of Accreditation is a deliverable from the AA to the laboratory and that the laboratory uses it as a public document to indicate the Fields of Testing for which they are accredited. Several individuals requested a copy of the proposed language changes. At the committee's request, Ms. Greene prepared a summary of the proposed language changes for the committee's distribution to interested parties.

CONCLUSION

The allotted meeting time having expired, Dr. Miller again encouraged volunteers to serve on the committee and thanked everyone for their input. The committee meeting was adjourned at 2:30 p.m. EST.

Attachment A

ACTION ITEMS
REGULATORY COORDINATION COMMITTEE MEETING
DECEMBER 16, 1999

Item No.	Action	Date to be Completed
1.	The Regulatory Coordination Committee will formulate a recommendation to the NELAC BoD that USEPA and the NELAC Quality Systems Committee evaluate the impact of the USEPA mandatory Quality System on NELAC laboratories and states.	4/30/00
2.	The Regulatory Coordination Committee will review the sample laboratory accreditation application currently posted on the NELAC Internet site.	5/31/00
3.	The Regulatory Coordination Committee will consider development of model generic SOPs and Quality Manuals for small laboratories.	Ongoing
4.	The Regulatory Coordination Committee will proceed with their proposal for restructuring the NELAC Scope of Accreditation.	Ongoing
5.	The Regulatory Coordination Committee will review the USEPA October 1999 Regulatory Agenda.	7/1/2000
6.	The Regulatory Coordination Committee will collect and evaluate recent state regulations and legislation for the implementation of NELAC.	7/1/2000

Attachment B

PARTICIPANTS
REGULATORY COORDINATION COMMITTEE MEETING
DECEMBER 16, 1999

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Attachment C

Restructuring of the NELAC Fields of Testing

The NELAC Regulatory Coordination Committee proposes that the NELAC Scope of Accreditation be defined by matrix and test method. To this end, the committee has drafted proposed language changes for the NELAC Program Policy and Structure and Accreditation Process Standards as follows:

Proposed changes to the Program Policy and Structure Standard:

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- Replace "method" with "analyte," "analyte" with "matrix," and "matrix" with "method" in Section 4.1.4.c.